REMARKS

This communication is responsive to the final Office Action dated October 29, 2008. Claims 4–9, 11, 12, and 15–24 are pending. Claims 4–9, 11, 12, 15, and 16 are currently withdrawn.

In view of the following remarks, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims set forth in the final Office Action.

Allowable Subject Matter

In the Final Office Action, the Examiner objected to claim 24 as including subject matter that would be allowable if rewritten in independent form. Applicant declines to amend claim 24 at this time, but thanks the Examiner for his indication of the allowability of claim 24.

Claim Rejections Under 35 U.S.C. §§ 102(b) and 103(a)

In the final Office Action, claims 17–19 , 22 and 23 were rejected under 35 U.S.C. § 102(b) as being anticipated by Schuelke et al. (U.S. Pat. No. 5,755,742; herafter "Schuelke"). In addition, claim 20 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Schuelke in view of Paul et al. (U.S. Pat. No. 5,814,088; hereafter "Paul"). Applicant respectfully traverses these rejections. Schuelke fails to disclose each and every feature of the inventions defined by claims 17–19 , 22 and 23, as required by 35 U.S.C. § 102(b). Furthermore, Shuelke in view of Paul would not have rendered the combination of features recited by claim 20 obvious to a person of ordinary skill in the art at the time of Applicant's invention, as required by 35 U.S.C. § 102(a).

Independent Claim 17

For example, Schuelke fails to teach or suggest a method of lead status monitoring in an implantable medical device (IMD) comprising the steps of sensing signals along two distinct sensing pathways, collecting data relating to one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant, and processing the collected data in accordance with an algorithm having an integrated set of rules to determine if a lead status event has occurred, as recited by Applicant's claim 17. According to claim 17, each rule of the set applies a specific determination criterion to a particular aspect of the collected data. Further, according to claim

17, a first determination criterion is applied for signals sensed along a first sensing pathway of the two distinct sensing pathways, and a second determination criterion is applied for signals sensed along a second sensing pathway of the two distinct sensing pathways.

In support of the rejection of claim 17, the Examiner characterized Schuelke as disclosing a system that allows for sensing in multiple pathways. According to the Examiner, the system described by Schuelke senses a P-wave amplitude and processes the data for each pathway to determine if there is a lead related event.[1] Applicant respectfully disagrees with the Examiner's characterization of the system disclosed in Schuelke and interpretation of the limitations of Applicant's claim 17.

For example, Applicant's claim 17 recites a step of processing the collected data to determine if a lead status event has occurred. According to Applicant's claim 17, the collected data relates to one of a percent of time in mode switch, R-wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant. Thus, Applicant's claim 17 requires processing one of these types of data to determine if a lead status event has occurred.

While the Examiner was correct in stating that Schuelke discloses sensing a p-wave amplitude, Schuelke in no way discloses or suggests processing the p-wave amplitude to determine if a lead status event has occurred. Schuelke discloses measuring the p-wave amplitude as part of monitoring a patient's heart rhythm for determining whether anti-bradycardia pacing, anti-tachycardia pacing, or anti-tachyarrhythmia shocks are needed to correct the patient's abnormal heart rate.[2] Schuelke does not disclose or suggest that the p-wave may be processed to determine if a lead status event has occurred. Schuelke also fails to disclose or suggest processing any other of the data recited in Applicant's claim 17, including a percent of time in mode switch, R-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant. In fact, Schuelke only discloses processing impedance of a conductive path to determine whether lead failure has occurred.[3] Processing impedance to determine lead failure is materially different from, and not suggestive of, Applicant's claimed method, which requires processing data relating to one of a percent of time in mode switch, R-

[1] Final Office Action mailed October 29, 2008, page 2, lines 11-15.
[2] Schuelke, column 8, line 66 to column 9, line 7.
[3] *See, e.g., Id.* at column 14, lines 5-37.

wave amplitude, P-wave amplitude, reversion pace count, refractory sense count, high rate episode count, and time from implant to determine if a lead status event has occurred.

Furthermore, Schuelke does not disclose or suggest a method in which processing the collected data includes applying a first determination criterion for signals sensed along a first sensing pathway of the two distinct sensing pathways and applying a second determination criterion for signals sensed along a second sensing pathway of the two distinct sensing pathways, as required by Applicant's claim 17. To the extent Schuelke discloses any method of determining lead integrity, Schuelke discloses applying the same impedance measurement for each conductive pathway that is being measured. In particular, Schuelke describes measuring a voltage V_m and a current I_m and calculating an apparent impedance of the lead under test from the V_m and I_m.[4] The apparent impedance is then compared to threshold impedance values, and the lead integrity is inferred from this comparison.[5] This same process is applied for each of the leads.

Independent Claim 22

Schuelke also fails to disclose or suggest the requirements of Applicant's independent claim 22. Applicant's independent claim 22 recites a method including, in part, determining whether a number of sensed events occurring along a first sensing pathway formed by one or more of a plurality of electrodes is greater than a first threshold associated with the first sensing pathway to generate a first event count. The method recited by independent claim 22 also includes determining whether a number of sensed events occurring along a second sensing pathway formed by one or more of the plurality of electrodes, different from the first sensing pathway, is greater than a second threshold associated with the second sensing pathway to generate a second event count. According to independent claim 22, the method further includes identifying the presence of a lead-related condition in response to the first event count and the second event count.

Similar to the rejection of Applicant's independent claim 17, the Examiner characterized Schuelke as disclosing a system that allows for sensing in multiple pathways and processes the

[4] *Id.* at column 15, lines 9-14.
[5] *Id.*

data for each pathway to determine if there is a lead related event.[6] Applicant respectfully disagrees with the Examiner's rejection of independent claim 22 over Schuelke.

For example, Schuelke fails to disclose or suggest determining whether a number of sensed events occurring along a sensing pathway formed by one or more of a plurality of electrodes is greater than a threshold associated with the sensing pathway to generate an event count, as required for each of the first and second pathways by claim 22. In fact, Schuelke even fails to disclose or suggest anything regarding a number of sensed events. As described above, Schuelke discloses comparing an apparent impedance of a lead to a threshold impedance value to determine the integrity of the lead. However, this is different than Applicant's claimed method, which requires determining whether a number of sensed events is greater than a threshold to generate an event count. Schuelke does not suggest that a number of sensed events is determined based on the impedances measured according to its method, and therefore clearly fails to suggest comparing such a number of sensed events to a threshold number to generate a count.

Schuelke also fails to disclose or suggest identifying the presence of a lead-related condition in response to the first event count and the second event count, as required by Applicant's independent claim 22. As described above, Schuelke tests the integrity of a lead by determining the apparent impedance of the lead. Schuelke describes that the impedance for each lead is measured independently and calculated from a single measurement. Schuelke fails to disclose or suggest any other method of identifying the presence of a lead-related condition. Schuelke does not disclose or suggest determining any sort of count of events for a lead, and certainly does not disclose or suggest identifying the presence of a lead-related condition in response to the first event count, which is for a first sensing pathway, and the second event count, which is for a second sensing pathway different from the first sensing pathway, as required by Applicant's independent claim 22.

Dependent Claims 18–21 and 23

Initially, Applicant notes that claims 18–21 and 23 depend from claims 17 and 23, respectively, and are in condition for allowance for at least the reasons presented above with respect to claims 17 and 22. In addition, the dependent claims introduce additional limitations that the applied references neither disclose nor suggest.

[6] Final Office Action mailed October 29, 2008, page 2, lines 11–15.

Applicant also notes that the final Office Action did not substantively address dependent claim 21. Dependent claim 21 requires the step of processing the collected data in accordance with an algorithm having an integrated set of rules to determine if a lead status even has occurred to comprise assigning weighted values to the collected data sets and summing the assigned weighted values to determine if one of a plurality of lead status events has occurred.

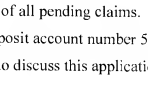
Schuelke fails to disclose or suggest the requirements of Applicant's claim 21. In particular, Schuelke fails to disclose or suggest assigning weighted values to the collected data sets. As described above, Schuelke is directed towards determining the integrity of a lead by comparing an apparent impedance of the lead to threshold values. The apparent impedance value is calculated from a measured voltage and a measured current. Schuelke fails to disclose or suggest any other method of determining lead integrity, and certainly does not disclose or suggest assigning weighted valued to collected data sets and summing the assigned weighted values to determine if one of a plurality of lead status events has occurred. For at least these reasons, Schuelke fails to disclose or suggest the requirements of Applicant's claim 21.

For at least these reasons, the Office Action has failed to establish a prima facie case for unpatentablility of Applicant's claims 17-24 under 35 U.S.C. §§ 102(b) or 103(a). Reconsideration and withdrawal of these rejections is respectfully requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: December 16, 2008

By: 

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